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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,880	09/28/2001	Tasuku Honjo	06501-088001 / JI-101DP2P	4273

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EXAMINER
SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 04/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,880	HONJO, TASUKU ET AL	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action, Paper No. 15, replaces the Election/Restriction requirement of Paper No. 13.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 9-18, in part, drawn to DNA encoding mouse cytidine deaminase, and vectors, and host cells comprising said DNA, classified in class 435, subclass 252.3.

II. Claims 1-5 and 9-18, in part, and 34-38, drawn to DNA encoding human cytidine deaminase, and vectors, and host cells comprising said DNA, classified in class 435, subclass 252.3.

III. Claims 6-8, in part, drawn to mouse cytidine deaminase protein, classified in class 435, subclass 227.

IV. Claims 6-8, in part, drawn to human cytidine deaminase protein, classified in class 435, subclass 227.

V. Claims 19-33, in part, drawn to antibodies to mouse cytidine deaminase, pharmaceutical compositions thereof, and hybridomas producing said antibody, classified in class 424, subclass 185.1.

VI. Claims 19-33, in part, drawn to antibodies to human cytidine deaminase, pharmaceutical compositions thereof, and hybridomas producing said antibody, classified in class 424, subclass 185.1.

VII. Claims 40-47, in part, methods of identifying regulators of mouse cytidine deaminase transcription, classified in class 435, subclass 6.

VIII. Claims 40-47, in part, methods of identifying regulators of human cytidine deaminase transcription, classified in class 435, subclass 6.

IX. Claims 48 and 49, in part, drawn methods of identifying regulators of cytidine deaminase activity, classified in class 435, subclass 18.

X. Claim 39, drawn to pairs of oligonucleotides primers, classified in class 536, subclass 24.33.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

Invention I is unrelated to Inventions II, IV, V, VI, and X because, the products of Inventions II, IV, V, VI, and X are physically and functionally distinct chemical entities from the DNA of Invention I.

Invention II is unrelated to Inventions III, V, VI, and X because, the products of Inventions III, V, VI, and X are physically and functionally distinct chemical entities from the DNA of Invention II.

Invention III is unrelated to Inventions IV, VI, and X because, the products of Inventions IV, VI, and X are physically and functionally distinct chemical entities from the protein of Invention III.

Invention IV is unrelated to Inventions V and X because, the products of Inventions V and X are physically and functionally distinct chemical entities from the protein of Invention IV.

The antibodies of Inventions V and VI are distinct because they are physically and functionally distinct chemical entities.

The pairs of oligonucleotide primers of Invention X is distinct from the antibodies of Inventions V and VI because the primers are physically and functionally distinct chemical entities from the antibodies.

The nucleic acids of Inventions I and II are related to the proteins of Invention III and IV, respectively, by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although each DNA molecule and protein pair are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Inventions III and IV are related to the antibodies of Inventions V and VI, respectively, by virtue of being the cognate antigen necessary for the production of antibodies. Although each protein and antibody pair are related, due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct

chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists or antagonists of the enzyme.

The methods of Inventions VII, VIII, and IX are independent as they comprise different steps, utilize different products and/or produce different results.

The method of Invention VII is independent from the products of Inventions II, III, IV, V, and VI because said method can neither use nor be used to make said products.

The method of Invention VIII is independent from the products of Inventions I, III, IV, V, and VI because said method can neither use nor be used to make said products.

The method of Invention IX is independent from the products of Inventions I, II, III, IV, V, and VI because said method can neither use nor be used to make said products.

The methods of Inventions VII and VIII are related to the DNAs of Inventions I and II, respectively, as a product and process of using. However, said methods are distinct from the respective DNA because the DNA can also be used for recombinant production of the encoded protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to the following patentably distinct species of fragments of a human cytidine deaminase gene:

For Group II,

SEQ ID NO: 9,

SEQ ID NO: 10,

SEQ ID NO: 11,

SEQ ID NO: 12,

SEQ ID NO: 13,

SEQ ID NO: 14,

SEQ ID NO: 15,

SEQ ID NO: 35,

SEQ ID NO: 18,

SEQ ID NO: 19,

SEQ ID NO: 20,

SEQ ID NO: 21,

SEQ ID NO: 22,

SEQ ID NO: 23,

SEQ ID NO: 24,

SEQ ID NO: 25,

SEQ ID NO: 26,

SEQ ID NO: 27,

SEQ ID NO: 28,

SEQ ID NO: 29,

SEQ ID NO: 30,

SEQ ID NO: 31,

SEQ ID NO: 32,

SEQ ID NO: 33, or

SEQ ID NO: 34.

And primer pairs of Group X

SEQ ID NOs: 31 and 32,

SEQ ID NOs: 20 and 22,

SEQ ID NOs: 21 and 30,

SEQ ID NOs: 24 and 25,

SEQ ID NOs: 23 and 27,

SEQ ID NOs: 23 and 28,

SEQ ID NOs: 23 and 29,

SEQ ID NOs: 26 and 27,

SEQ ID NOs: 26 and 28,

SEQ ID NOs: 34 and 29,

SEQ ID NOs: 33 and 29, or

SEQ ID NOs: 18 and 19.

If applicants elects Group II, applicant is required under 35 U.S.C. 121 to elect a single disclosed species of human cytidine deaminase gene fragment for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If applicant elects Group X, they are required to elect a single primer pair for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic although, each generic claim does not encompass all species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan L. Swope Ph.D.